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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/786,679 | 02/25/2004 | Nicholas J. Bate | 1587 | 3609 |

27310 7590 09/26/2006

PIONEER HI-BRED INTERNATIONAL, INC.
7250 N.W. 62ND AVENUE
P.O. BOX 552
JOHNSTON, IA 50131-0552

| EXAMINER | |
|---|---|
| WORLEY, CATHY KINGDON | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/786,679 | BATE ET AL. | |
| | Examiner | Art Unit | |
| | Cathy K. Worley | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *13-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a nucleic acid, an expression cassette, a transgenic plant and transgenic seed, classified in class 435, subclass 419, for example.

II. Claim 13-30, drawn to a method for expressing a polynucleotide in a plant, classified in class 800, subclass 287, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid molecule and expression cassette of group I could be used for a materially different process, for example, it could be used to produce protein in a wheat germ extract through *in vitro* transcription/translation.

A search for the methods of group II will require searching for methods of expressing polynucleotides in plants. A search for the products of group I will require searching for transgenic plants with the recited phenotypes. These searches

are not coextensive, and therefore it would constitute an undue burden to examine these groups together.

The examiner has required restriction between product (group I) and process (group II) claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not

be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Karen Varley on April 24, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

*Specification*

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should specify the gene and organism from which the promoter has been taken.

3. The abstract of the disclosure is objected to because it is not descriptive enough. The abstract should be between 50 and 150 words in length, and the abstract should specify the gene and organism from which the promoter has been taken. Correction is required. See MPEP § 608.01(b).

4. The use of the trademarks CLOROX and GELRITE has been noted in this application. They should be written in all capital letters wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "a transgenic seed of the plant of claim 7" does not specify what transgene is comprised by the seed. Does the transgenic seed comprise SEQ ID NO:1? Or does the transgenic seed comprise some other, unrelated, transgene?

6. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-12 are drawn to an isolated nucleic acid molecule comprising at least 55 contiguous nucleotides of SEQ ID NO:1 or comprising a sequence having at least 70% identity to SEQ ID NO:1 or comprising a polynucleotide that hybridizes to the complement of SEQ ID NO:1, and to expression cassettes, vectors, plant cells, seeds, and plants comprising said nucleic acid molecule.

The nucleic acid of the invention is described as a promoter that is specific to the embryo surrounding region (ESR) of endosperm (see page 2 lines 25-27),

therefore the essential feature of the invention is that the nucleic acid comprises promoter activity in the ESR.

The invention is directed to molecules that function as a promoter, and therefore each embodiment must comprise promoter activity. The specification does not describe any fragments of SEQ ID NO:1 as small as 55 contiguous nucleotides known to retain the function of promoter activity, nor does the specification describe any nucleic acid sequences having 70% identity to SEQ ID NO:1 that are known to have promoter activity. The recitation of any nucleotide sequence comprising at least 55 contiguous nucleotides of SEQ ID NO:1 encompasses 143,916 molecules. In addition, the recitation of nucleic acids with only 70% identity allows for 30% of all bases to be changed. Thirty percent of the 590 bp of SEQ ID NO:1 is 177 bases. This encompasses any combination of A, G, T, or C at 90 different positions, which includes $4^{177}$ molecules ($3.7 \times 10^{106}$). Therefore, the genus of molecules that is claimed in the instant encompasses multitudes of molecules. However, the applicants have only described one molecule, which is SEQ ID NO:1. This does not constitute a representative number.

In addition, the applicants have not provided any guidance about what structures are required for the promoter activity. The specification describes a bioinformatics approach that identified motifs that are conserved between the instant SEQ ID NO:1 and promoters from the prior art (see page 14), however, no experiments were performed to show that these motifs are sufficient for promoter

activity. With no description of a structure/function relationship between certain subsequences and the promoter function, and with only one molecule described out of the multitudes of molecules included in the claimed genus, the written description requirements have not been met.

7. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising SEQ ID NO:1, does not reasonably provide enablement for any other promoter comprising any 55 contiguous nucleotides of SEQ ID NO:1 or having at least 70% identity to SEQ ID NO:1 or hybridizing to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-12 are broadly drawn to an isolated nucleic acid molecule comprising 55 contiguous nucleotides of SEQ ID NO:1 or comprising a sequence having at least 70% identity to SEQ ID NO:1 or hybridizing to SEQ ID NO:1, and to expression cassettes, vectors, plant cells, seeds, and plants comprising said nucleic acid molecule.

The specification compares the sequence of SEQ ID NO:1 with other promoters that are known in the art, and the specification discloses that some of the conserved motifs are present in SEQ ID NO:1, while others are absent from SEQ ID NO:1 (see page 14). These elements are distributed throughout the 590 base-pair

molecule of SEQ ID NO:1; at positions 135-139, 274-278, 552-556, 248-253, 447-452, 412-417, and 449-455 (see page 14).

The specification discloses that the promoter of SEQ ID NO:1 was isolated from maize genomic DNA using the UNIVERSAL GENOME WALKER kit (see paragraph bridging pages 39-40). The specification discloses in situ hybridization that demonstrated the tissue-specificity of the endogenous transcript from the maize INVINH1 gene (see Figure 1, page 39 lines 9-13 and page 40 lines 5-23). The specification also discloses several prophetic examples for the transformation of plants with the ESR-preferred promoter of the invention operably linked to a gene of interest (see pages 40-49).

However, the specification does not disclose fragments retaining promoter activity and having only 55 contiguous nucleotides of SEQ ID NO:1 or having as many as 177 nucleotides substituted within SEQ ID NO:1 which constitutes 70% identity to SEQ ID NO:1. Nor does the specification teach any nucleic acids that hybridize to SEQ ID NO:1 and have promoter activity. The specification also does not teach minimal functional promoter regions derived from SEQ ID NO:1. Even minor alterations can alter promoter activity. Kim et al. (Plant Mol. Biol., 1994, Vol. 24, pages 105-117) teach that the deletions of just a few nucleotides can abolish promoter activity (page 109). The Applicant's disclosed analyses of conserved domains would suggest that there may be many different cis-elements necessary for the functionality of the instant promoter. In the absence of further guidance, one

skilled in the art is left to randomly produce an endless number of substitutions and deletions of nucleotides from SEQ ID NO:1, which is undue experimentation.

Fifty-five base-pair long regions of a DNA fragment that has promoter activity cannot predictably be assumed to also have promoter activity. Deletion analysis of various promoters have shown that even DNA segments from the portion of a promoter region containing sequence elements thought to be most important (*e.g.*, the TATA-box) need to be longer than 55 basepairs. Maiti et al (1997, Transgen. Res., 6:143-156), in studies on a figwort mosaic virus promoter, found that smallest portion upstream of the transcriptional start site of that would support transcription was 198 basepairs long; segments of 73 and 37 basepairs did not work (Fig. 4).

Given the breadth of the claims encompassing any nucleic acid molecule from the huge genus described above that retains promoter activity, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one of skill in the art to make and use the invention as claimed.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bonello et al. (Gene (2000) Vol. 246, pp. 219-227).

Claim 1 is drawn to an isolated nucleic acid molecule comprising a polynucleotide which initiates transcription in a plant cell and comprises a sequence that hybridizes under "stringent" conditions to the complement of SEQ ID NO:1.

Bonello et al. teach promoters from Esr genes (see page 224, Figure 4). These promoters comprise sequences that have the inherent characteristic of being able to hybridize to the complement of SEQ ID NO:1 under conditions of some stringency. The instant specification does not define "stringent" conditions, but merely exemplifies some possible choices of conditions (see page 19), therefore, the hybridization conditions are not defined and any conditions are encompassed by the current recitation.

9. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaudhary et al. (WO 01/16340, published on March 8, 2001).

Claims 1-12 are drawn to an isolated nucleic acid molecule comprising 55 contiguous nucleotides of SEQ ID NO:1 or comprising a sequence having at least 70% identity to SEQ ID NO:1 or hybridizing to SEQ ID NO:1, and to expression cassettes, vectors, plant cells, seeds, and plants comprising said nucleic acid molecule.

Chaudhary et al. teach an isolated nucleic acid capable of directing seed-specific expression in a plant comprising a nucleic acid sequence that hybridizes to

any one of 4 sequences disclosed in their application (see claim 14). SEQ ID NO:1 of the instant application would hybridize to the sequences disclosed in their application. Conversely, as discussed above, the stringency conditions in the instant application have not been defined, and therefore, the sequences taught by Chaudhary et al. are encompassed by the claims in the instant application.

Chaudhary et al. teach a expression cassette (see claim 15) and a vector (see claim 22). They teach a plant cell, a transgenic plant, and a seed comprising the promoter, and they teach monocots, including corn, barley, wheat, oat, sorghum, and rice (see claims 17-20). They teach the expression of a gene that results in an alteration of fatty acid composition in the seed (see claim 12), and they teach the expression of many different proteins, including vaccines which are gene products that confer pathogen resistance when administered to animals (see page 16, line 31).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
September 6, 2006

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER